DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFI 35 M42970

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER
VIA EXPRESS MAIL

OCT 20 2000

Mr. Avtar Photay, Director
PSP Dental Company, LTD.
3-5 Dylan Road, Belvedere
Kent DA17 5QS
UNITED KINGDOM

Dear Mr. Photay:

During an inspection of your firm located in Kent on July 3-5, 2000, our investigator determined that your firm manufactures dental compounds used for cements, fillings, and impression material. These are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) requirements set forth in the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

21 CFR 820.250 Statistical techniques

Failure to establish and maintain procedures for identifying valid statistical techniques when using a sampling plan for inspection of the final packaged product. This observation was made during our September 1994 inspection. The current inspection found that there continues to be no statistical rationale for the sampling plan used to inspect finished packaged product.

21 CFR 820.70(c) Environmental control

Failure to establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70. For example, floors, storage shelves, raw materials, and various production equipment were observed to have a heavy buildup of powder residues.

21 CFR 820.70(g) Equipment

Failure to establish and maintain adequate procedures for the cleaning of equipment, as required by 21 CFR 820.70(g). For example, the high speed mixer's maintenance book indicated that the last time the mixer was cleaned was on July 4, the date of our inspection.

However, photographs taken while the machine was not in operation on that date showed a white residue on the surfaces of the mixer. The dough mixers showed a white and pink cake like residue encrusted on the outside surfaces, illustrating a lack of having been cleaned. The cleaning procedures and records for the [redacted] Siever were found to still be deficient, even though this was identified as a deficiency during the September 1994 inspection.

We also have concerns relative to the adequacy of your internal audit procedure as required by 21 CFR 820.22 and your corrective and preventive action procedure, required by 21 CFR 820.100. In view of the fact that cleaning of manufacturing equipment was an issue during the September 1994 inspection, as was the need for a statistical rationale for sampling, and these areas remain as issues during this last inspection means that PSP's quality audit and corrective and preventive action procedures are ineffective.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the form FDA 483. The effectiveness of the corrective actions you proposed will have to be evaluated during a follow-up inspection.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and its corresponding regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct deviations whether identified by our investigator or your internal systems audit. Failure to promptly correct these deviations may result in further action by the Food and Drug Administration.

Please notify this office in writing within 15 working days of receipt of this letter of the anticipated date that your facility will be ready for reinspection.

Your response should be sent to the attention of Ron Swann, Acting Branch Chief, Dental, ENT and Ophthalmic Devices Branch within the office indicated below at the U.S. Food and Drug Administration, 2094 Gaither Road, Rockville, Maryland 20850 or call 301-594-4613 ext. 109.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health